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HL

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/321,882	05/28/99	UPASANI	R 1483.0130002

HM12/1124  
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EXAMINER

BADIO, B

ART UNIT	PAPER NUMBER
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1616

7

DATE MAILED: 11/24/99

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
**09/321,882**

Applicant(s)  
**Upasani et al.**

Examiner  
**Barbara Badio**

Group Art Unit  
**1616**



- ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

- ☒ Claim(s) 1, 2, 25-29, 35-43, and 46-57 is/are pending in the application.
- Of the above, claim(s) 28, 29, 35-43, 47-53, and 56 is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 1, 2, 25, 26, 46, 55, and 57 is/are rejected.
- ☒ Claim(s) 27 and 54 is/are objected to.
- ☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- ☒ Notice of References Cited, PTO-892
- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 4
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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### First Office Action on the Merits

#### ***Election/Restriction***

1. Applicant's election with traverse of Group II in Paper No. 6 is acknowledged. The traversal is on the ground(s) that (a) 35 USC § 121 only applies to plural claimed inventions in different claims; (b) search and examination of Groups I and II would not present a serious burden to the examiner or the PTO, despite the different classification and (c) search of one or more methods of use along with the compound claims would not result in an undue burden on the examiner. This is not found persuasive because MPEP § 803.02 states "it is improper for the Office to refuse to examine that which applicants regard as their invention, *unless the subject matter in a claim lacks unity of invention.*" Unity of invention exists where compounds included within a Markush group (1) share a common utility and (2) share a *substantial structural feature* disclosed as being essential to that utility. The claimed compounds do not share a **substantial** structural feature. The common core of the claimed compounds is a steroid ring. Attached to the steroid ring are numerous substituents which differ vastly. Thus, as set forth in MPEP § 803.02, the claims lack unity of invention and restriction is proper.

Applicant's argument of a lack of undue burden on the examiner to search Groups I and II together is noted. However, because the compounds are classified

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differently, a search of one group would not result in a search of the other and, thus, a reference against one may not be applicable to the other.

Applicant's argument in regards of a search of one or more methods of use along with the compound claims is also noted. The examiner notes that a reference against the compounds may not be applicable to the method of use of the instant compound. However, upon allowance of the compound claims, method claims of the same scope will be rejoined with the compounds allowed.

The requirement is still deemed proper and is therefore made **FINAL**.

2. Claims 28, 29, 35-43, 47-53 and 56 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention, the requirement having been traversed in Paper No. 6.

### ***Double Patenting***

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double

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patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1 and 2 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 5,925,630. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to overlapping subject matter (i.e., some of the compounds recited by the instant claims are recited in claims 1-21 of U.S. Patent No. 5,925,630).

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims ~~1, 2~~, 25, 26, 46, 55 and 57 are rejected under 35 U.S.C. 102(b) as being anticipated by Hosoda et al.

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Hosoda et al. teach  $3\alpha$ -hydroxy-21-[(tetrahydro-2H-pyran-2-yl)oxy]-pregnan-20-one (see attached Abstract). The compound taught by the reference is encompassed by the instant claims.

***Allowable Subject Matter***

7. Claims 27 and 54 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

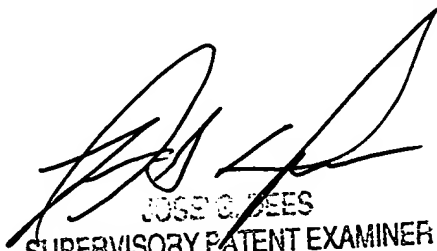
***Telephone Inquiry Contacts***

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara Badio whose telephone number is (703) 308-4595. The examiner can normally be reached between 7:30 am and 4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, José Dees, can be reached on (703) 308-4628. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

BB  
November 22, 1999

  
JOSÉ C. DEES  
SUPERVISORY PATENT EXAMINER  
1616